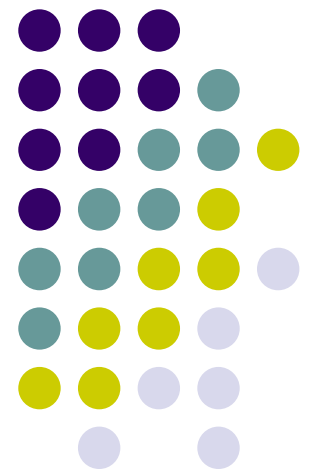


IPBS / NBN Informatics Needs and Vision

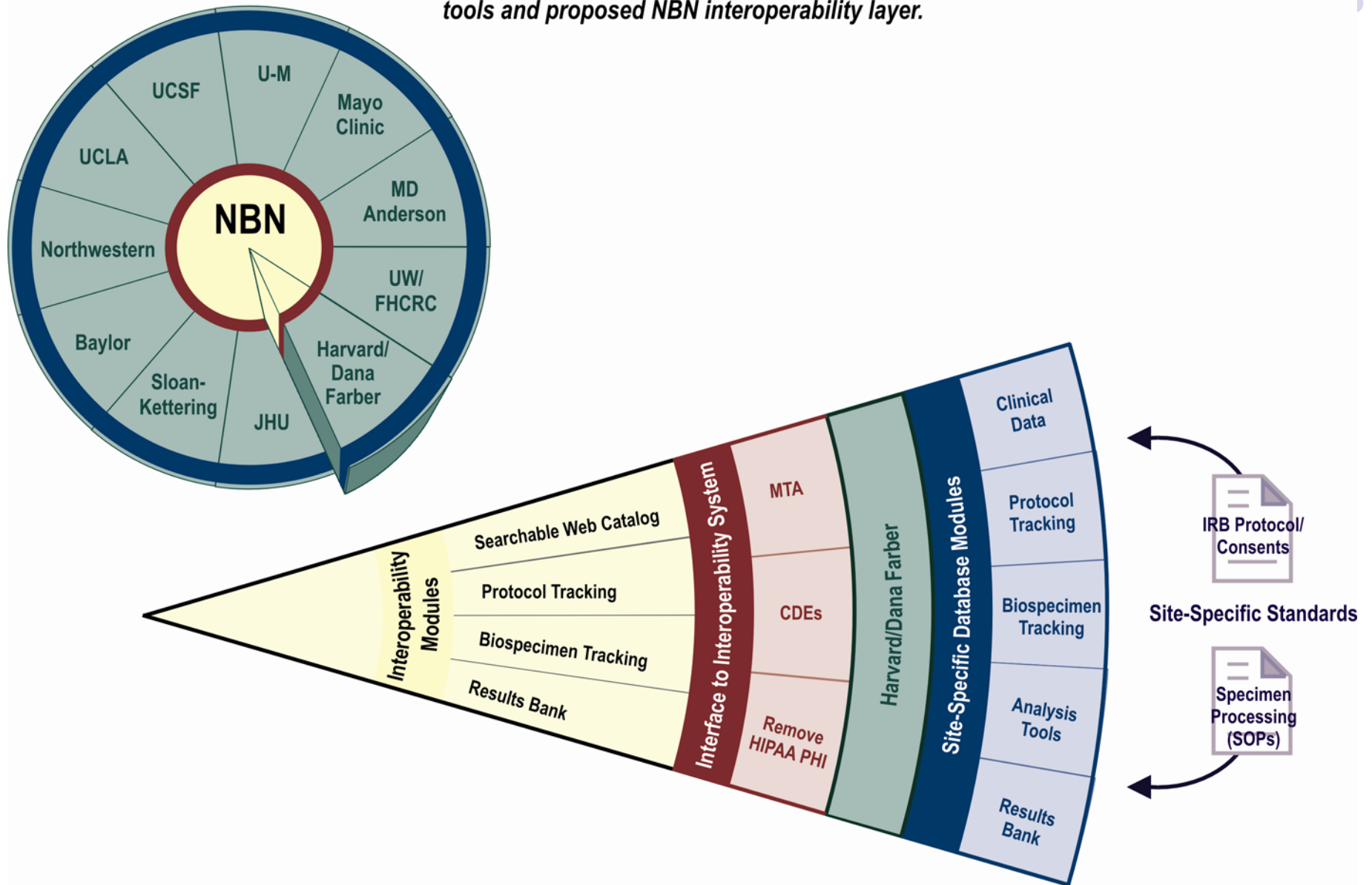
Paul Fearn

Memorial Sloan-Kettering Cancer Center



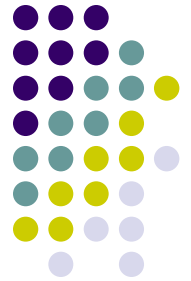
Prostate SPORE NBN Pilot Overview

Relationship between existing prostate SPOREs information tools and proposed NBN interoperability layer.



IPBS / NBN

Standards / Requirements



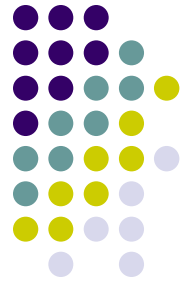
NBN

- Standard NBN protocol / consent template
- Standard operating procedures template
- Standard MTA template

Site-Specific

- “Standardized” NBN protocol / consent
- “Standardized” operating procedures (SOPs)
- “Standardized” MTA
- IPBS protocol review

Site-Specific IPBS / NBN Informatics Requirements



- Track screening/eligibility (optional)
- Track IPBS registrations/accruals
 - Consents
 - PHI at local site
- Clinical data
 - Clinical CDEs
 - Records of biospecimen collection
 - Longitudinal follow-up

Site-Specific IPBS / NBN Informatics Requirements, II



- Specimen Tracking
 - Specimen CDEs
 - Exact location and amount
 - Processing/handling (chronological)
 - Status (reserved/published to NBN)
 - Shipments sent/received
 - Laboratory
 - Responsible contact
 - Dates / times

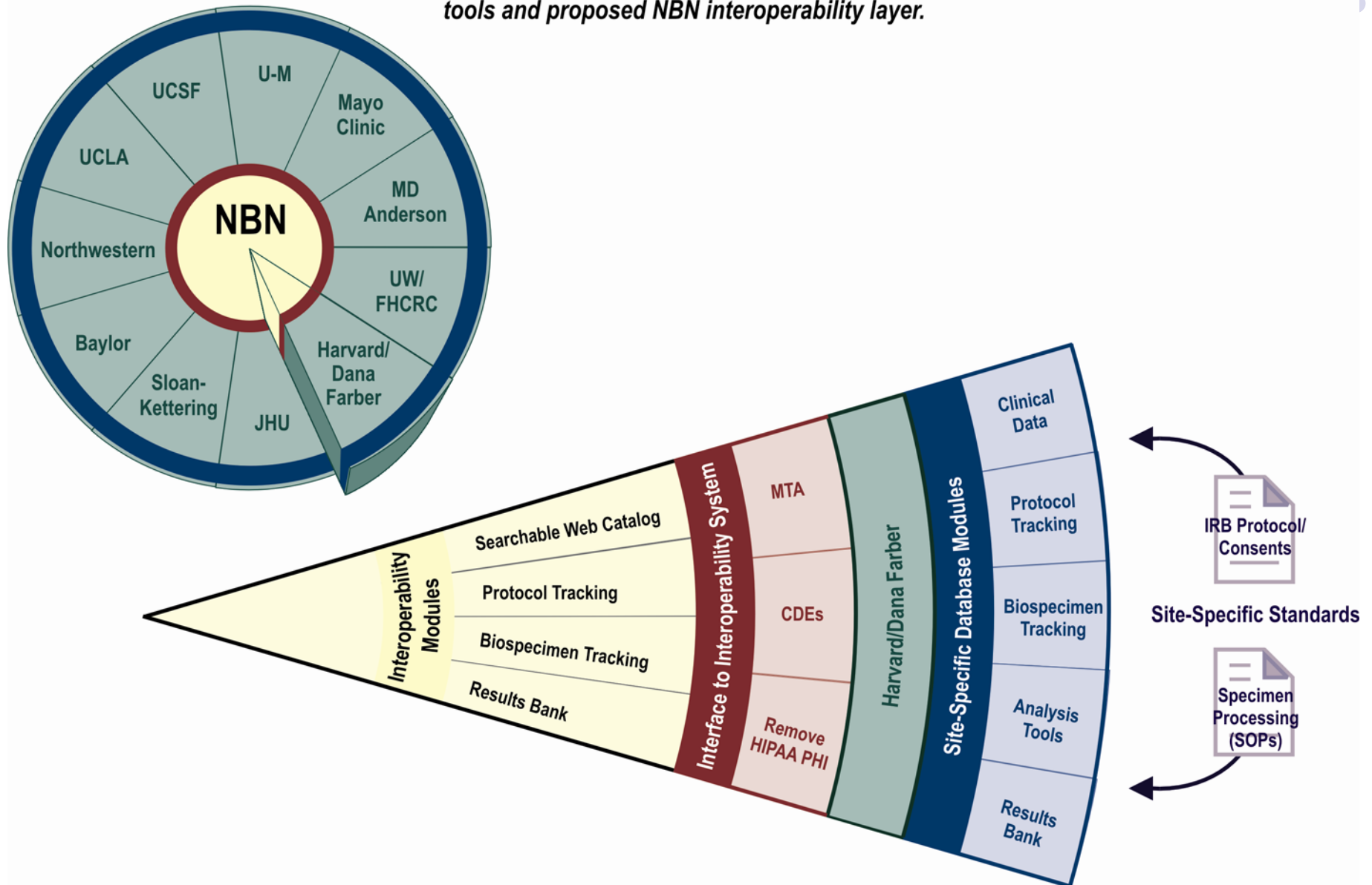
Site-Specific IPBS / NBN Informatics Requirements, III



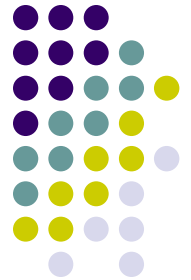
- Analysis tools
 - Laboratory specific
 - General
 - Pathology focus
 - Bioinformatics focus
- Results bank
 - Index by gene, protein, patient
 - Curated

Prostate SPORE NBN Pilot Overview

Relationship between existing prostate SPOREs information tools and proposed NBN interoperability layer.



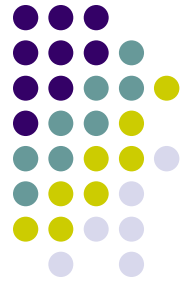
Interface to NBN: Privacy and Security Issues



- Remove HIPAA Protected Health Information
- Dataset specific case identifiers
- Relative dates
- Maintain linking file at local site

Interoperability Modules

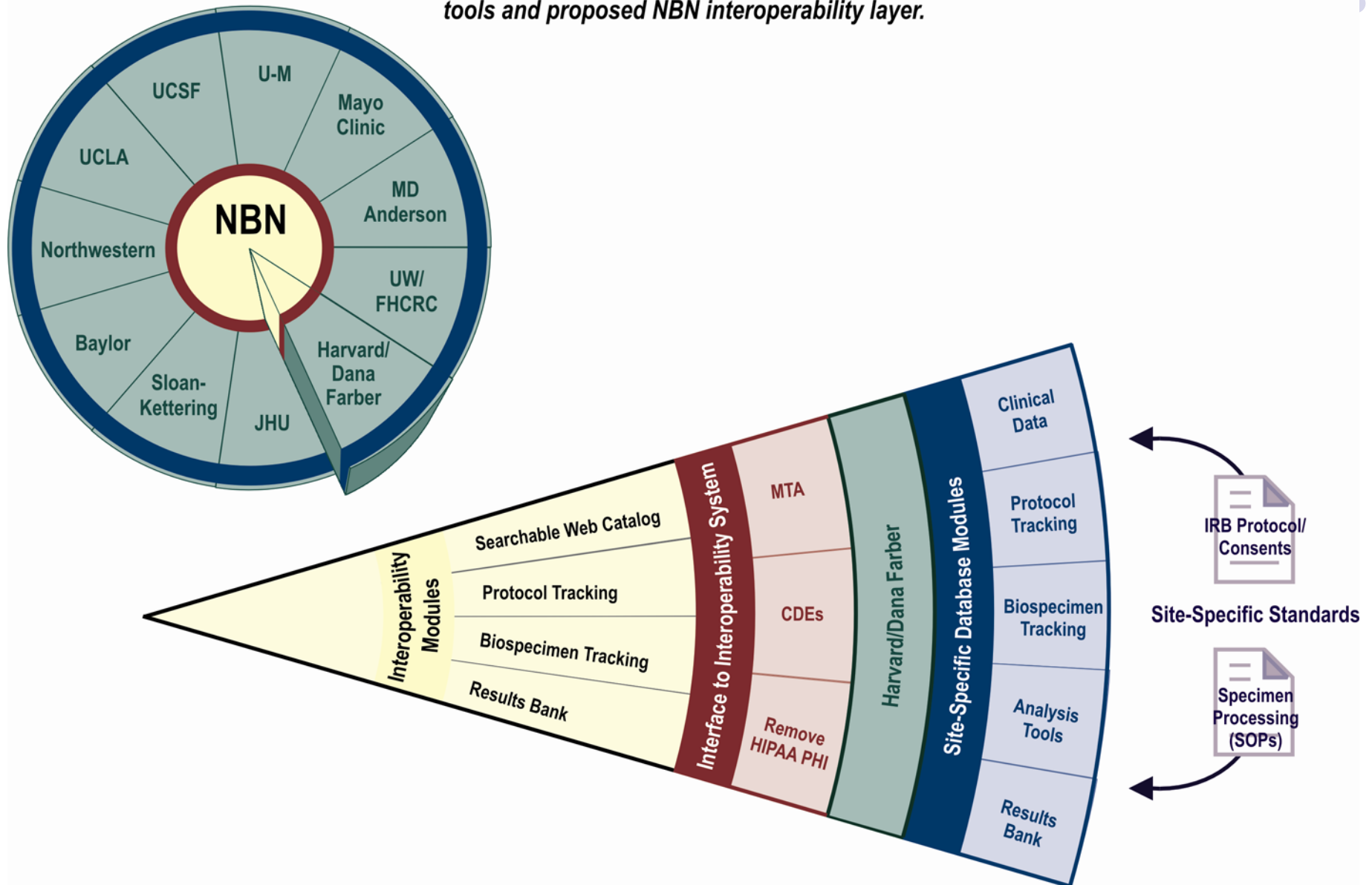
IPBS / NBN Requirements

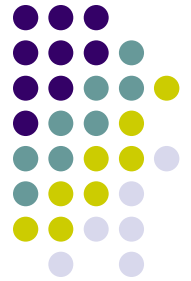


- Searchable specimen catalog
- Protocol tracking
 - Accruals
 - Progress
- Biospecimen tracking
 - Distributions
- Results bank
 - Submissions / updates
 - Searches

Prostate SPORE NBN Pilot Overview

Relationship between existing prostate SPOREs information tools and proposed NBN interoperability layer.





Agenda

8:20am – 8:30am

- IPBS / NBN Informatics Needs and Vision

8:30am – 9:00am

- **Interoperability Standards, NBN and caBIG**
 - John Speakman, MSKCC
 - Mark Adams, Booz Allen Hamilton
 - Sharon Settneck, SAIC

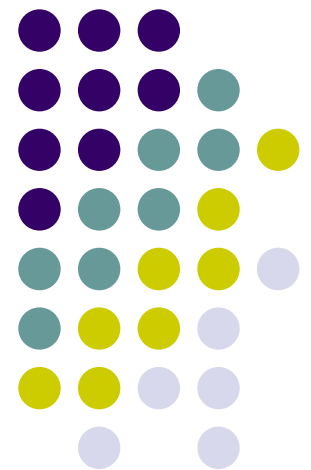
9:00am – 10:00am

- Informatics System Presentations

Informatics System Presentations Overview

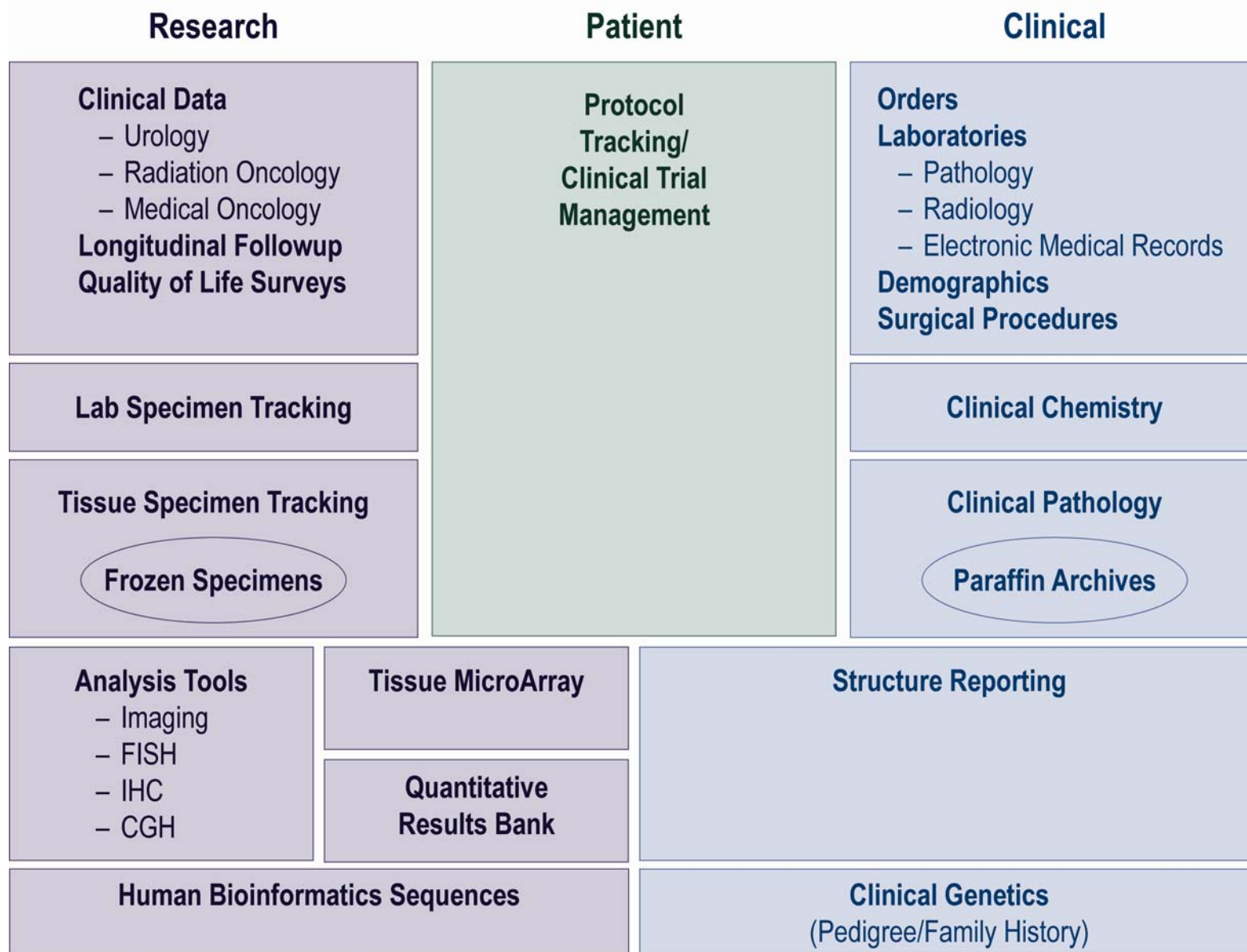
Paul Fearn

Memorial Sloan-Kettering Cancer
Center





Site-Specific Module Relationships



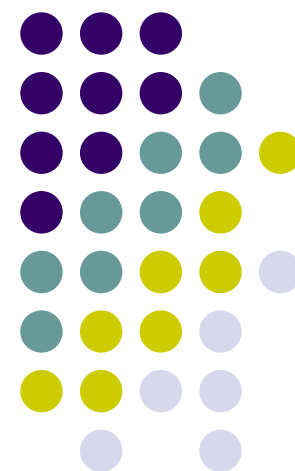
Informatics System Presentations



- Overview
 - Understand systems
 - Identify expertise / resources
 - Consider systems relative to IPBS / NBN scope
- 12 minutes to present
- 3 minutes Q & A
- Alphabetical order

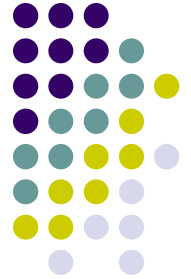
Memorial Sloan-Kettering Cancer Center

Paul Fearn, Caisis
John Speakman, CRDB



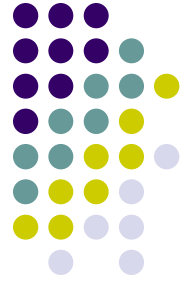
Caisis Overview

www.caisis.org



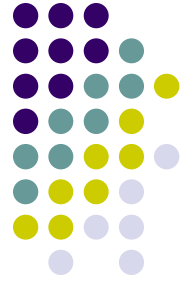
- Project Goals
- CDEs
- Design
- Project History
- Version 2.2
- CaisisDB
- Version 3.0
- Next Steps

Caisis Project Goals

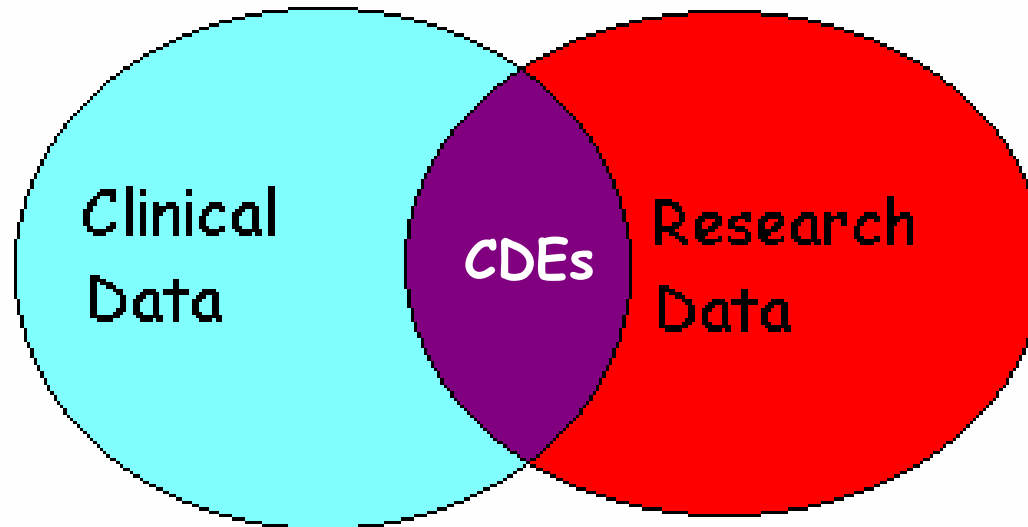


- Integrate research with clinical practice
- Reduce user bias built into system
- Integrate disciplines / departments
- Facilitate inter-institutional collaboration
 - Open source development
 - Open source license

Prostate Cancer Common Data Elements



A chronological patient history composed of common data elements (CDEs) for clinical practice and research

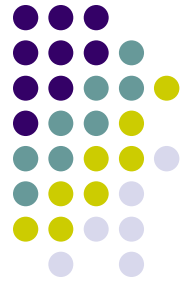




Prostate Cancer Common Data Elements*

- Patient's demographics: MRN, DOB, Ethnicity, Family Hx.
- All relevant biochemical markers
- All physical exam (DRE) results
- AJCC/UICC Clinical Tumor Stage by physician
- All relevant biopsies with pathologic findings
- All relevant diagnostic imaging studies and findings
- All relevant radiation therapy
- All relevant surgical procedures with pathologic findings
- All relevant medical therapy and concomitant meds
- All quality of life assessments (urinary/sexual/bowel function)
- Vital status by date

*Cancer Location, Volume, Aggressiveness and Treatments over time.



Caisis Data Entry Design

- Integrated, chronological CDEs
- Less interpretation/calculation
 - Selecting baseline values
 - Calculating outcomes, progression
- Partial dates (mm/yyyy) and fuzzy values (<)
- Data quality
- Notes / comments
- Justify blank fields
 - unknown, not available
 - not interpretable, not obtainable
- Full auditing
- Record locking by users



Vocabulary Control Design

0° of freedom

- Check box, radio buttons,
- Select box

1° of freedom

- Combo box, fixed list

2° of freedom

- Combo box, fixed list
- Review new items

3° of freedom

- Combo box, fixed list
- User can add new items

4° of freedom

- Combo box
- List items from table

5° of freedom

- Text box

☒ Adjuvant: No BCR/LCR/Mets
☐ Adjuvant: < Adjuvant Months

Biopsy Findings

☐ Diagnostic
☒ Pre-Treatment

Diagnoses/Comorbidities:

Hypertension	PreTx
Rising cholesterol	PreTx
Renal cancer	09/23/1998

Data Quality:

OUT	outside
REV	performed outside, MSK review
STD	performed and reviewed at MSK
RR	research review, highest quality

Prim. Gleason:	3
Sec. Gleason:	4
Gleason Sum:	7



Caisis Project History

- Microsoft Access
 - 1999 ProstateDB 1.0
 - 2000 PRDB / Prostabase
 - 2003 ProstateDB 1.2 (10 institutions)
- ColdFusion / SQL Server
 - 2002 Valhalla 1.0 – 1.1
 - 2003 Valhalla 1.2 (3 institutions)
- Microsoft.NET
 - 2004 Caisis 2.0 – 2.2
 - Integrated prostate, bladder, kidney, testis data
 - Billing/EMR compliant clinic forms
 - 2005 Caisis 3.0 under development

Caisis, Version 2.0 – 2.2



Valhalla: Patient Data - Microsoft Internet Explorer

Address: http://smskdw03:8006/valhalla/PatientData/index.aspx?patientId=1559&findClicked=true

Current Patient: Joey Clinic 441679BE Find a Patient: [Search]

Help Log Out

PATIENT LISTS PATIENT DATA FORMS REPORTS

Common Tasks Patients Encounters Procedures Therapies / Tx Diagnostics

View: List All Filters On [X]

Date	Variable	Value	Quality
12/23/2002	PSA	23	
01/01/2003	COMBO		
01/07/2003	DRE	Chest NON_DX	
01/07/2003	CHEMO	adenovirus vectors	MSKCC
01/07/2003	Status	RisingPSA_Castrate	MSK
01/08/2003	Albuterol		MSKCC
01/17/2003	CON		MSKCC
01/17/2003	CON		MSKCC
01/22/2003	DRE	Prostate	
02/04/2003	Absorption Base		
02/04/2003	Erectile Dysfunction		
02/11/2003	PSA	2.1	STD
02/27/2003	Status	LCR	
03/01/2003	Endoscopy	Partial	
03/03/2003	PLND	Chest ABN_MAL	
03/03/2003	MRI	Chest ABN_MAL	
03/03/2003	PLND	Chest ABN_MAL	OUT

Surgeries > Endoscopies for Joey Clinic

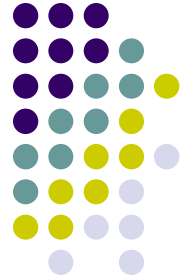
CPT Code: [Dropdown]
 CPT Description: [Text]
 Surgeon: Dr. Magee [Dropdown]
 Path #: [Text]
 Date: 03/01/2003 [Calendar]
 Time: 3/1/2003 12:00:00 AM [Text]
 Type: Partial [Dropdown]
 Indication: [Text]
 Result: good [Dropdown]
 Stage System: [Dropdown]
 Stage T: [Dropdown]
 Grade: [Dropdown]
 Morphology: [Dropdown]
 CIS: [Dropdown]

Pathology Findings

expand new edit save lock cancel delete

Entered By: Alip @ 11/7/2003 2:32:00 PM
 Updated By: soullif @ 1/5/2004 1:32:52 PM
 Locked By:

Done Local intranet



Caisis Clinical Templates

- Collect structured data for research
- Billing / clinical documentation
- Populated
- HPI algorithms
- Data feeds from institutional systems
 - Labs
 - Demographics
 - Appointments

CaisisDB Data Export Control Panel



Data Export

Patient Selection | Progression Clock | BCR / DT | Options | Privacy / Export File | Browse Values

Start Clock

☐ Dx Biopsy
☒ **RP**
☐ XRT Start Date
☐ XRT Stop Date
☐ Brachytherapy

☐ Post RP BCR
☐ Post RP XRT (Salvage XRT)
☐ Post XRT BCR
☐ Post XRT RP (Salvage RP)
☐ Post Brachy BCR

Second Line (Salvage)

☐ Post RP Horm
☐ Post RP Chemo
☐ Post XRT Horm
☐ Post XRT Chemo
☐ Post Brachy RP
☐ Post Brachy XRT
☐ Post Brachy Horm
☐ Post Brachy Chemo

Rank Stop Clock (ProgEvent)

1	<input checked="" type="checkbox"/> Biochemical (BCR)	<input type="checkbox"/> physician
2	<input checked="" type="checkbox"/> Local (LCR)	<input type="checkbox"/> sensitive
3	<input checked="" type="checkbox"/> Metastasis	<input type="checkbox"/> sensitive
4	<input checked="" type="checkbox"/> Surgery (salvage RP)	
5	<input checked="" type="checkbox"/> Rad Tx (salvage)	<input type="checkbox"/> Adjuvant Rad Tx
6	<input checked="" type="checkbox"/> Horm Tx (salvage)	<input type="checkbox"/> Adjuvant Horm Tx
7	<input checked="" type="checkbox"/> Chemo Tx (salvage)	<input type="checkbox"/> Adjuvant Chemo Tx
8	<input checked="" type="checkbox"/> Survival	

Data Export

Patient Selection | Progression Clock | BCR / DT | Options | Privacy / Export File | Browse Values

Dataset Purpose

☒ Data Exploration
☐ Data Review Preparatory to Research
☐ Research Data Analysis
☐ Operations Data Analysis

Dataset Privacy Level

☒ De-Identified Data Set
☐ Limited Data Set
☐ Identified Data Set

IRB Approval Type

☐ Research Authorization (Protocol)
☐ Waiver of Authorization
☐ Data Review Preparatory to Research
☐ Data Use Agreement
☒ None

IRB Approval Date:

☒ Export Analysis Table
☐ Export Segments Table
☐ Export Data Tables

Dataset Name:

Export File Folder:

Export File Name:

Secret Decoder Folder:

Data Export

Patient Selection | Progression Clock | BCR / DT | Options | Privacy / Export File | Browse Values

Biochemical recurrence (BCR) definition

Num PSA Rises:
 PSA Threshold:
 Last rise over:
 Total PSA Rise:
 Absolute BCR Level:
 Rounding:
 Rise over nadir:

☒ Use LiJa PSA thresholds
 0.6 before 2/13/1996
 0.2 after 2/13/1996
 * set PSA Threshold to 0.2

Count Rises

☒ Peaks
☐ Non Consecutive Rises
☐ Only Rises

Transformation

☒ Natural log
☐ Log base x
☐ Cube root
☐ Square root
☐ None

x inverse

Exclusions

☐ Prostatitis
☐ Acute retention
☐ double PSAs on 5 alpha reductase inhibitor

Indicate BCR on:

☐ Nadir
☒ Interpolate between nadir and 1st rise
☐ Use 1st rise, 1st detectable value
☐ Use last value, last rise

☒ Early Censoring

CaisisDB Data Export Output



Microsoft Access - [Analysis : Table]											
File Edit View Insert Format Records Tools Window Help											
Type a question for help											
AnonymousID	BxGG1	BxGG2	BxGGS	PreTxPSA	ClinT_Stage	NeoAdjHormTx	RP_Date	AdjHormTx	ProgFreeTime	ProgEvent	
2014153870	3	3	6	28.1	T1C		12/01/1997		19.58153	BCR_Algorithm	
606685431	3	3	6	4.5	T1C		11/17/1997		49.70948	NO	
495959404			7	99	T3B	LHRH					
-1787603971	3	3	6	3.7	T1C		12/31/1997		50.2023	NO	
-1325723270				5.1			01/06/1997		63.2457	NO	
710258291			6	0.6	T1C						
160103480			7	3.8	T1C	AALHRH					
-2113362471	3	3	6	4	T1C						
-1715069658	3	3	6	4.5	T2A		11/07/2001		4.303993	NO	
293815215	3	3	6	5.5	T1C		11/21/2001		3.384056	NO	
-1012785212	3	3	6	10.9	T2B		10/25/2001		0	NO	
688500085	3	4	7	16	T3	AALHRH	10/22/2001		0	NO	
-1127572590	3	3	6	6.8	T1C		12/11/2001		13.30624	NO	
-1042119509	3	3	6	9.4	T1C		12/04/2001		10.84212	NO	
-1413286896	3	3	6	5	T2A		11/15/2001		8.673697	NO	
210454225				17.8							
-1252312898											
-813453977				12.7	T2A		11/13/2001		14.75185	NO	
1588593948	3	4	7	5.5	T1C		11/02/2001		4.303993	NO	
-2071458323	3	4	7	7	T2B		01/06/2003		0	NO	
581787818	3	3	6	3.2	T1C		12/07/2001		13.73335	NO	
903002595				0.4							
315399912	3	3	6	8	T2B		11/02/2001		4.846099	BCR_Algorithm	
1455185609	3	3	6	5.4	T1C		01/14/2002		9.49507	NO	
25509718	3	3	6	4.9	T2A						
-1563204065	3	3	6	4.1	T2B		11/27/2001		9.002246	NO	
-1180119692	3	4	7	4.2	T1C		12/04/2001		5.322495	NO	
1682068837	3	3	6	5.9	T1C		12/11/2001		14.98184	NO	
1486995650	3	3	6	4.9	T1C		11/26/2001		10.02075	NO	
-836948453				36.9							
-1303552832	3	4	7	3.1	T2A		11/02/2001		12.05775	NO	
1223544257				15.5							
-471297810	3	3	6	7.5	T2A		12/04/2001		2.135569	NO	
395791831	3	3	6	17.8	T2A		12/21/2001		6.603837	NO	

Record: 1 of 5 of 8112
Datasheet View

CaisisDB

Longitudinal Follow-Up



Post-Treatment Survey

Page1 Page2 Page3 Page4 Page5 Page6 Page7 Page8 Page9

Count of patients who need follow-up letters by surgeon:

	Surgeon	NeedLetter1	NeedSSDI	NeedTumReg
				2
	BOCHNER		1	6
	DALBAGNI		50	14
	DONAT		15	10
	EASTHAM		23	87
	FAIR	1	80	48
	GONG		1	2
	Guillonau			22
	HERR		57	19
	LARCHIAN			1
	MORSE		1	1
	outside			1

Record: 1 of 17

Interval: 14 mo

1. Select a Surgeon:

Open Table of NeedSSDI/NeedTumReg

Prostate
Bladder

Display Stats

Cancel Previous Next

Post-Treatment Survey

Page1 Page2 Page3 Page4 Page5

ENVELOPE RECEIVED / RETURN TO SENDER

Open letter and determine MRN and institution, save envelope for return address / post-mark date

Find patient in Valhalla <http://cancerdb.mskcc.org>

Was letter returned to sender?

☐ Yes, enter a "ReturnedToSender" Action
Trigger changes PtContactStatus to NeedPtContactInfo

☐ No, Enter "LetterReceived" Action on date letter was received (or today's date if unknown)
Trigger changes PtContactStatus to "LetterReceived", next page

If letter "ReturnedToSender", was there a forwarding address?

☐ Yes, update address in Patient Info tab, enter a "AddressUpdated" Action
Trigger changes PtContactStatus to "NeedLetterx" (last NeedLetter Status) or whatever is needed

☐ No, Throw it away in HIPAA bin, next page

Cancel Previous Next

Post-Treatment Survey

Page1 Page2 Page3 Page4 Page5

Getting items ready to send to MD

FOR FAXING

1. Print out fax coversheet and coverletter

Print Fax Coversheet

Print Coverletter

2. Fax Coversheet, letter and signed authorization to Drs. office.

3. File away the package that was faxed along with the fax receipt

4. Enter MD_LetterFaxed in the actions tab.

5. Change the patient's contact status to MD_Contacted.

Cancel

FOR MAILING

1. Print out coverletter

Print Coverletter

2. Print out address label in Word and place on envelope

3. Put coverletter, authorization, and return envelope in the envelope

4. Enter MD_LetterSent in the actions tab

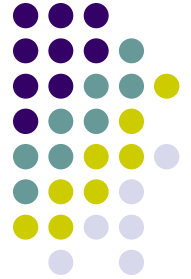
5. Change the patient's contact status to MD_Contacted.

6. Bring to building mailroom

Previous Next

Caisis, Version 3.0

- Electronic forms for physicians
- Protocol tracking



Caisis Operative Details Form



Physician: Dr. Peter Scardino[View Your OR List for Today](#)[View Session Report](#)[Help](#)[Log Out](#)

Patient: John Doe **MRN: 80065505**

Prostatectomy Form

General Details

- Date
- Case Surgeon
- Anesthesia
- Procedures Performed

Prostatectomy Details

- Intraoperative Prostate Exam
- UICC Stage
- MRI
- Accessory Vessels
- Neurovascular Bundles
- Doppler Probe
- Vesicourethral Anastomosis
- Drains
- PostOp Prediction

Preview for Approval

Prostatectomy Form for John Doe

OR Date 09/15/2004

Case Surgeon Dr Peter Scardino

Anesthesia

ASA Score

Anesthesia Type ☐ General ☐ Epidural ☐ Combined

Procedures Performed

Procedure	Surgeon	Surgeon Type	Assistant	Assistant Type
Prostatectomy	P. Scardino	Attending	F. Bianco	Fellow

Caisis Operative Details, II



Physician: Dr. Peter Scardino[View Your OR List for Today](#)[View Session Report](#)[Help](#)[Log Out](#)

Patient: John Doe **MRN: 80065505**

Prostatectomy Form

- General Details
 - Date
 - Case Surgeon
 - Anesthesia
 - Procedures Performed
- Prostatectomy Details**
 - Intraoperative Prostate Exam
 - UICC Stage
 - MRI
 - Accessory Vessels
 - Neurovascular Bundles
 - Doppler Probe
 - Vesicourethral Anastomosis
 - Drains
 - Post-Op Prediction

[Preview for Approval](#)

Prostatectomy Form for John Doe

Intraoperative Prostate Exam

Side	Level	AP	Laterality	Cancer	ECE	+SM	FS Result	
Right								X
Right								X
Left								X
Left								X

[add](#)

UICC 1992 Stage

T-Stage

MRI

Veins Urethral Length

Accessory Vessels

Caisis Operative Details Note



Physician: Dr. Peter Scardino		View Your OR List for Today	View Session Report	Help	Log Out
Patient: John Doe		MRN: 80065505			

OR Report for 11/01/2004
Patient: John Doe

The text contained within this document has been generated based on data you have entered for this surgery. It is the physician's responsibility to review the text for correctness etc etc etc.

Click on a sentence / comment to edit the data.

Comments you previously entered are editable here.

Go Back

Approve This Form & Print for Signing

Preview: OR Report for John Doe pg1

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Aenean lectus odio, tristique nec, ultrices non, ornare quis, nulla. Praesent magna. Proin enim wisi, dapibus ut, volutpat id, viverra eu, mauris. Cras vel lorem id nunc vulputate tempor. Vestibulum venenatis scelerisque pede. Vestibulum accumsan. Cras nec ipsum sit amet ligula tristique lobortis. Ut est est, tristique at, vehicula sit amet, pharetra eu, diam. IntraOp examination showed Prostate Cancer definitely present.

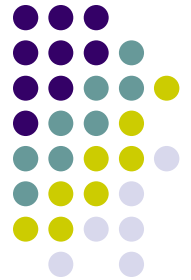
Nullam est ante, fermentum et, sodales sed, hendrerit vel, lorem. Vestibulum orci. Aenean mollis. Mauris fringilla, wisi ut eleifend vulputate, pede diam lacinia urna, sed mattis dolor arcu vel est. Aliquam tempus nonummy eros. Sed magna lacus, egestas ac, imperdiet ut, facilisis mattis, est. Nullam vitae lacus.

Comments

Removed wide margin fermentum mauris id nisl. Donec non enim id nibh consequat consequat.

Donec nisl. Neurovascular Bundles status rated as 46 (out of 100). Mauris ornare rutrum augue. Phasellus consectetur, enim consequat gravida convallis, leo elit laoreet ligula, nec vehicula est magna at dolor. Donec erat. Cras commodo augue in tortor. Duis ut leo. Donec fermentum mauris id nisl. Donec enim id nibh consequat consequat. Duis vitae tellus. Donec elementum. Nam nec est orci, ornare nec, interdum pharetra, molestie et, nunc. Quality of Vesicourethral Anastomosis, rated as 4 (out of 4) in the judgement of the surgeon. Nulla ac urna. In vel lorem a elit, aliquet elementum. Class aptent taciti sociosqu ad litora torquent per conubia nostra, per inceptos hymenaeos. Vivamus neque ligula, interdum non, porttitor eget,

Caisis Protocol Schema Items



Schema Items for Protocol 01-064

Create New Schema Item

Item Short Name

What type of item is this?

☒ The new item can be categorized as:

- Actions
- Dietary Intake
- Surveys
- Encounters
- Biopsy
- Endoscopy
- QOL Tx
- Diagnostics / Imaging
- Medications**
- Lab Tests
- Physical Exam

☐ The new item is a protocol action that does not fit into the categories found on the left.

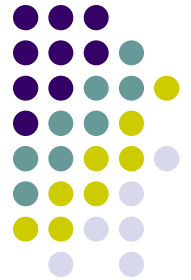
Create New Schema Item

Current Items for This Schema

- Viagra QOL Treatment**
Medication Name = "Viagra"
Dose = 100
Units = mg
- Lab Tests**
PSA
ACP
LDH

Save Item List And Begin Schema Schedule

Caisis Schema Item Scheduling



Schema Schedule for Protocol 01-064 Intervals

Schema Items	Timeline					
	Week 1 ± 3 Days	Week 2 ± 3 Days	Week 3 ± 3 Days	Week 4 ± 3 Days	Week 5 ± 3 Days	Week 6 ± 3 Days
Medical History	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Physical Exam	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Vital Signs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Height	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Adverse Event Evaluation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PSA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
ACP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LDH	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
WBC	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Caisis Protocol Calendar



November 2004						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	1	2	3	4	5 Nerve Bonitas	6
7	8 John Doe William Jersey Edgar Poe	9	10 John Cack	11 Geoffrey Jack Zoe Milligan	12	13
14	15 Joseph Stains	16 Jery Bladderman Eric Livinda Shelley Locke Eduard Minerza Don Umbers	17	18 Geoffrey Jack Zoe Milligan	19 Ruben Merced Sally Chiu George Bonitas	20
21	22 Edgar Poe	23 Brett Aelman John Doe Paul Sherman	24 John Cack Helissa Furch Vanessa Johnson	25 Hunry Hill Rodney Neefhan	26 Jonery Ell Frank O'C Carlton Bonitas Brock Landers Jackie Voss	Month 3 Not Yet Scheduled. Allowable Date Range is highlighted. Click for more info.
28	29 Ernie Punkard Mabury West	30 John Odinkor Josh Mosh Derek Warck				

November 16, 2004 (by Protocol)

Click on a Patient to View.
Patients in Gray have not yet been scheduled.

01-064

[View Schema Definition](#)

Jery Bladderman

Shelley Locke

Eduard Minerza

Michael Tannen

Stanley Yelnats

04-019

[View Schema Definition](#)

Jery Bladderman

Eric Livinda

Don Umbers

Mark Jakid



Caisis Protocol Visit Checklist

John Doe

Month 6 for Protocol 01-064
Scheduled for 11-08-2004

[View Previous Visit](#)

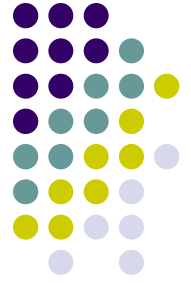
[View / Schedule Next Visit](#)

Schema Items for Month 6

Event	Date
<input checked="" type="checkbox"/> <u>Physical Exam</u>	11-08-2004
<input checked="" type="checkbox"/> <u>Vital Signs</u>	11-08-2004
<input checked="" type="checkbox"/> <u>Weight</u>	11-08-2004
<input type="checkbox"/> Performance Status	11-08-2004
<input type="checkbox"/> CBC w/diff, plts	11-08-2004
<input type="checkbox"/> PT/INR	11-08-2004
<input type="checkbox"/> Serum Chemistry	11-08-2004
<input type="checkbox"/> Adverse Event Evaluation	11-08-2004
<input checked="" type="checkbox"/> <u>PSA</u>	11-08-2004

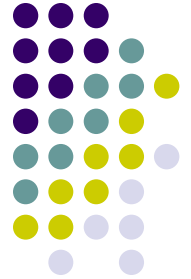
Check off items as they occur to create the corresponding pending records in the database. You may enter data for a checked item by clicking on the link or by using the step-by-step workflow below.

[Enter Data Via Workflow](#)



Next Steps for Caisis

- Data model improvements
 - Meta-data fields
 - Procedures section
 - caBIG compatibility
- Specimen tracking (UW/FHCRC)
- Better distinguish clinical and research data
- Electronic clinic forms (for physicians)
- “Intelligent” data entry
- Automated longitudinal follow-up



MSKCC Patient Web Forms

- Quality of life questionnaires
- IPSS / IIEF
- Longitudinal follow-up
- Medications
- Allergies
- Comorbidities
 - PMH
 - PSH

Acknowledgements

MSKCC

- Paul Alli – Database Administrator (DBA)
- Jason Fajardo – Graphic Designer / Programmer
- Paul Fearn – Project Leader
- David Kuo – Network, Hardware, Software Support
- Kevin Regan – Project Manager / Programmer
- Frank Sculli – Lead Developer
- Hee Song Seo – Data Feeds, Data Output Manager
- Mark Snyder – Data Model Design
- Kinjal Vora – Data Entry Manager
- Brandon Smith - Programmer

UW/FHCRC

- Derek Walker – Project Manager
- Mike Bauer – Programmer / Project Manager
- Scott Koon – Lead Programmer
- Ric Johnston – Project Manager
- Agnes Gawne – Data Manager
- Bret Dodson – Technical Writer

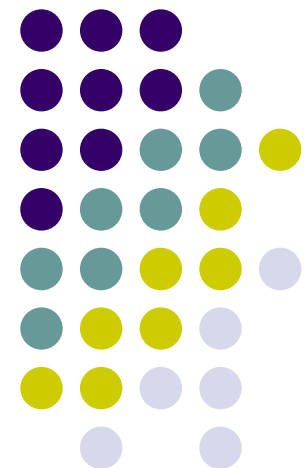
Baylor

Leonor Guarata – Data / Project Manager
Marlin Mixon – Programmer
Jimmy Xie – Database Administrator (DBA)

New York Prostate Institute / Haliard

Louis Potters, MD – President

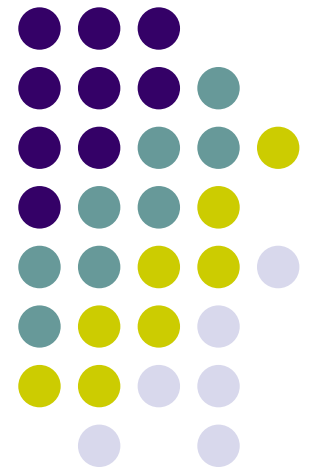
Frank Sculli – Lead Programmer
Sally Yang – Programmer
Kevin Regan – Project Manager



Physicians: Peter Scardino, Howard Scher, Michael Kattan, Victor Reuter, Louis Potters, Urology and GU/Medicine Faculty and Fellows, University of Washington / FHCRC (Tia Higano, Paul Lange,) Baylor College of Medicine (Kevin Slawin, Seth Lerner) et al.

Memorial Sloan-Kettering Cancer Center

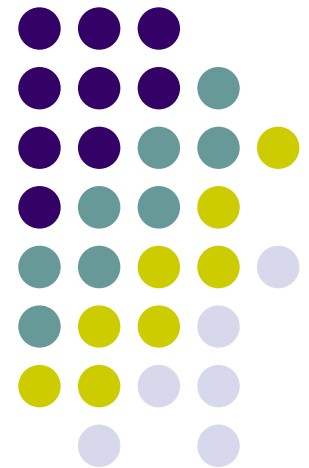
Paul Fearn, Caisis
John Speakman, CRDB

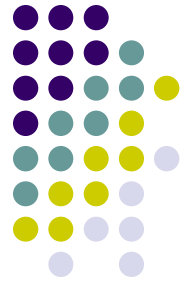


12:45pm to 1:15pm

Partnerships Working Groups

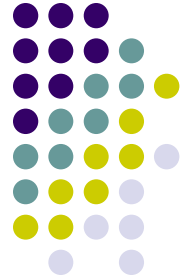
Mark Rubin, Dana Farber
Paul Fearn, MSKCC





Inter-SPORE Partnerships

- Purpose
 - Reduce duplication of effort
 - Reduce complexity of integration
 - Vocabulary
 - Fields
 - Interfaces
 - Isolate organizational culture effects
 - Reduce development costs
- Information systems focus



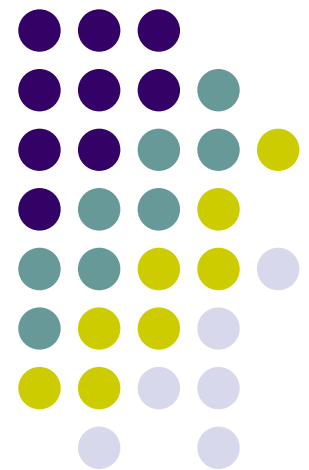
Informatics Partnerships

- Existing
 - MSKCC and UW/FH
 - UM and DF
 - PCCTC
- Potential
 - Who?
 - Why?
 - Next steps?

1:15pm to 1:45pm

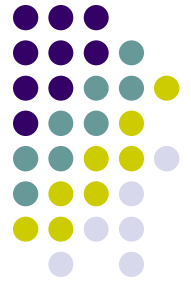
IPBS / NBN Use Cases

Paul Fearn, MSKCC



Use Case 1...

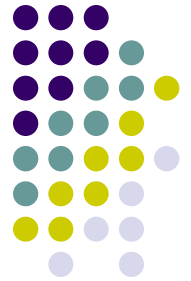
Prospective IPBS, New Patient



- Upload IRB documents, SOPs, MTA
- Check eligibility
- Enter clinical CDEs
- Enter specimen CDEs
- De-Identify CDEs and transmit to NBN
- Ship specimens to central lab
 - Attach MTA
- Receive specimens at central lab
- Process specimens at central lab
 - Enter specimen CDEs
- Ship specimens to SPORE sites

Use Case 1

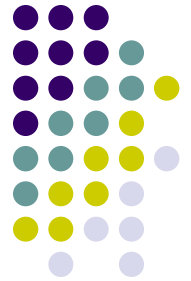
Prospective IPBS, New Patient



- Receive specimens at SPORE site
 - Download specimen CDEs
- Process and analyze specimens
 - Enter specimen CDEs
 - Enter analysis results
- Upload analysis results
- Analyze compiled results
 - Download clinical and specimen CDEs
 - Download analysis results from results bank

Use Case 2...

Prospective IPBS, New Specimen



- Enter new clinical CDEs
- Enter new specimen CDEs
- Ship specimens to central lab
 - Attach MTA
- Receive specimens at central lab
- Process specimens at central lab
 - Enter specimen CDEs
- Ship specimens to SPORE sites

Use Case 2

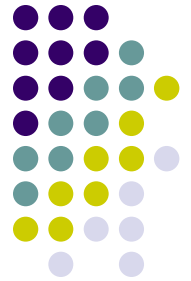
Prospective IPBS, New Patient



- Receive specimens at SPORE site
 - Download specimen CDEs
- Process and analyze specimens
 - Enter specimen CDEs
 - Enter analysis results
- Upload analysis results

Use Case 3...

Retrospective IPBS



- Search the catalog of available specimens
 - 200 RP and 200 XRT
 - 5 years longitudinal follow-up
- Select specimens to request
- Request specimens (min 50 per site)
- Review and approve requests at each site
- Check for complete CDEs
- Ship samples

Use Case 3

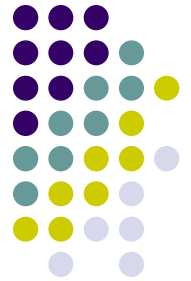
Retrospective IPBS



- Receive specimens
 - Enter specimen CDEs
- Process and analyze specimens
 - Enter specimen CDEs
 - Enter analysis results
- Upload analysis results
- Download compiled assay results
- Analyze and publish compiled results

Use Case 4

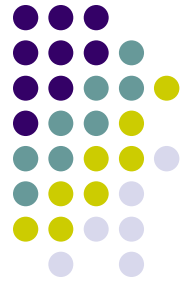
NBN Retrospective Project



- Search NBN pilot specimen catalog
- Select items to request
- Save session
- Resume session
- Request specimens
 - Submit project description
- Review request (Governance)
- Approve or deny request
- Check for CDEs
- Ship approved specimens

Use Case 5

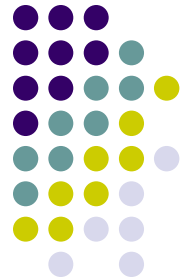
New Prospective Protocol



- Search published clinical CDEs on specimen catalog
- Save search criteria by user
- Submit prospective study proposal
 - Research question and methods
 - Indicate preferred institutions
 - Indicate required resources
- Review proposal (Governance)
- Approve or reject proposal

Use Case 6

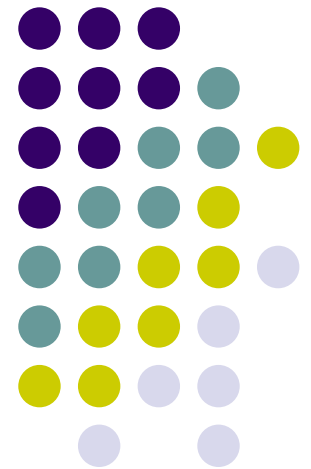
Publishing Specimens to NBN

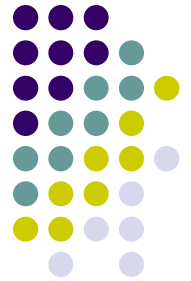


- Log onto NBN web site
- Indicate which sample to publish
- Authorize publishing of available samples
 - Terms of use
 - Include banked but not generally available?
- Enter CDEs
 - Minimal clinical CDEs
 - Minimal specimen CDEs
- Upload IRB consent, MTA, SOP if new
- Change status of published specimens

Path Forward

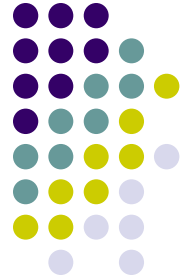
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Paul Fearn, MSKCC





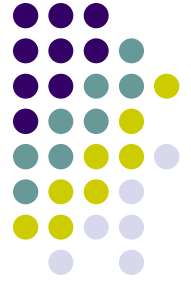
Next Steps

- Features / modules
 - Specimen tracking
 - Queries / reports / dataset production
- Standards / caBIG
 - CDEs / data dictionaries / vocabularies
 - Legal, IRB, documentation
 - Ownership
 - Privacy / security
 - Results data



Action Items & Timeline

- Specific action items
- Estimate of timeline
- Dependencies
- “Bottlenecks”
- Test cases



Discussion starters

- Data sharing project – report on series
- Real points of project connection with caBIG